

CLIA CORNER

State Hygienic Laboratory at The University of Iowa

Third Quarter 2020

In This Issue...

- Quality Assessment (QA) Overview
- Introduction to the Four Laboratory QA Systems
- Review of the General Laboratory System and Sample Audit Checklist

What is Quality Assessment (QA)?

It includes the activities, processes, checks, and balances implemented to ensure continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems. It is an on-going review process that encompasses all areas of the laboratory's technical and non-technical functions and all locations/sites where testing is performed.

What are CLIA's requirements for QA?

The laboratory must have a written QA policy that includes all four quality systems: general system, pre-analytic system, analytic system, and post-analytic system.



The QA policies and procedures should include: the practices/processes implemented for each QA system, a review of the effectiveness of corrective action taken to resolve problems when identified, the revision of policies and procedures necessary to prevent recurrence of problems, and discussion of the QA reviews with the appropriate staff.

QA practices/processes must include a component that ensures continuous improvement of the laboratory's performance and services through ongoing mechanisms to monitor, assess, and when indicated, correct problems.

Established policies, procedures and processes that comprise and monitor all four quality systems must be followed and documented.

Four QA Systems:

General

Pre-Analytic

Analytic

Post-Analytic

The General Laboratory quality system encompasses the general operational functions that are not specific to any one specialty or subspecialty. Below, each section of the system is reviewed and includes QA probes on which to focus.

Confidentiality of Patient Information: The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

QA Probes:

→ Visitor access to laboratory areas where patient information may be easily viewed

- Computer screens
- Printers/ fax machines
- Test requisitions, results, test result worksheets, etc. sitting on counters

→ Electronic record access

- Password protection for computer terminals, electronic health record (EHR) systems, laboratory information systems (LIS), etc.

→ Paper record storage systems including test requisitions, test result worksheets, laboratory logs, etc.

→ Release of patient test results



Specimen Identification and Integrity: The laboratory must ensure positive identification and optimum integrity of a patient's specimen from time of collection or receipt of the specimen through completion of testing and reporting of results.



QA Probes:

→ Proper specimen collection, handling and storage

- Review of manufacturer instructions for proper specimen type, collection device, handling, storage, etc.
- Patient education and instructions for special collections, e.g., timed collections, home collections, dietary restrictions, fasting, etc.
- Collection system alerts or manual system for identifying specimens with special handling or processing requirements e.g., cold

centrifugation, timed incubation, specimen to be kept on ice, non-exposure of specimen to air, addition of preservatives, etc.

→ Two patient identifiers throughout all phases of testing

- Confirmation of patient identification during the collection process, especially when patient identification information includes similar names, dates of birth, gender, etc.
- Ensuring specimens are labeled BEFORE leaving the collection area
- Labeling rapid test devices, tubes, slides, etc. during the testing process
- Minimization of specimen transfer and pour-off tubes
- Instrument printouts and test result worksheets

Complaint Investigations: The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

Areas to Consider:

→ **Problem/complaint receipt**

- Adequate system to allow patients/customers to report concerns
- System for documentation of problems/complaints

→ **Problem/complaint referral and mitigation**

- System for referral of problems/complaints to proper management, authority, reference laboratory, outside offices, etc. and documentation of notification to those sources
- Documentation of investigation and steps taken to mitigate problems/complaints within the laboratory's control, as appropriate
- Follow-up with complainant upon resolution



Communications: The Laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

QA Probes:

→ **Tracking and documentation system by the type of communication breakdown and facility involved**

- Test request with all pertinent patient information
- Patient preparation
- Specimen collection, handling, and transport

→ **Breakdown evaluation and notification system**

- System for notification to facilities with communication breakdown
- Suggested remediation for areas of concern
- Process change/improvement for repeat issues
- Education and training as necessary



Proficiency Testing (PT): The laboratory must review and evaluate PT results including all results not graded by the proficiency testing company. The laboratory must also verify the accuracy at least twice annually for all non-regulated analytes.

QA Probes:

→ **Laboratory test menu: regulated vs. unregulated specialties, subspecialties and analytes**

→ **PT enrollment for regulated specialties, subspecialties and analytes**

→ **Method of twice annual verification for unregulated specialties, subspecialties and analytes**

→ **Review and documentation of graded (acceptable and unacceptable) and ungraded PT test results**

→ **Review [Second Quarter 2019 CLIA Corner Newsletter](#) for more details about PT result evaluation and corrective action**



Personnel Competency: As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

QA Probes:

→ **Frequency and documentation of assessment**

- Twice within the first year of hire
- Annually thereafter

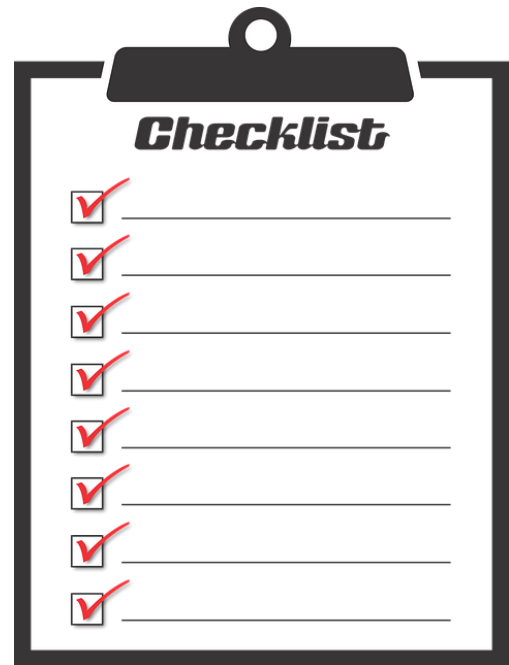
→ **Personnel to be assessed**

- Clinical consultant (moderate and high complexity)
- Technical consultant (moderate complexity)
- Technical supervisor (high complexity)
- General supervisor (high complexity)
- Testing personnel (moderate and high complexity)

→ **6 required criteria for testing personnel competency assessment**

- Direct observation of patient test performance
- Monitoring the recording and reporting of test results
- Review of test results/worksheets, quality control (QC) records, proficiency testing (PT) results, and maintenance records
- Direct observation of performance of instrument maintenance and function checks
- Assessment of test performance through testing previously tested specimens, internal blind testing samples or external PT samples
- Assessment of problem solving skills

→ **Review [1st Quarter 2018 CLIA Corner Newsletter](#) for more details about competency assessment**



An effective QA program is the key to a successful laboratory. As previously mentioned, laboratories must have written QA policies and procedures that include practices/processes with a component that ensures continuous improvement of the laboratory's performance and services through ongoing mechanisms to

monitor, assess, and when indicated, correct problems. A great way to accomplish this is with internal auditing tools. Remember that practices and processes established in the laboratory's QA policies and procedures must correspond to the laboratory's auditing tools, including specific activities and the frequency with which they are performed. Please see the attached example.

CONTACT US

If you would like to be added to our mailing list, email us at:

Kristine-Rotzoll@uiowa.edu

Or

Melinda-Bochmann@uiowa.edu

NOTE: This example has been created by the Iowa CLIA State Agency as an aid in laboratory QA processes and is not an official form or tool endorsed by the Centers for Medicare and Medicaid Services

(CMS). Laboratories are not required to utilize it, and are free to modify the tool as needed.

Stay tuned for the next issue of the CLIA Corner where we will discuss the second quality system: **Pre-Analytic**

Quality Assessment Audit: General Laboratory System

Policy/ Procedure/ Audit Tool Review	Yes	No	NA
Lab has a written policy/procedure for General System QA; includes audit criteria and frequency of review Document corrective action below, if needed:			
Written policy/procedure matches audit tool Document corrective action below, if needed:			
Patient Confidentiality: Walk Through & Observation			
Patients have access to lab areas where confidential info may be: computer screens, printers, faxes, requisitions/ labels/specimens on counters or in sight, etc. Document corrective action below, if needed:			
Can patients see computer screens or read lab logs/requisitions/specimen labels on the counter/fax machine/ printer when in the lab? Document corrective action below, if needed:			
Staff log out of computer terminals when not in use Document corrective action below, if needed:			
Patient test results released to patients according to lab/organization policy Document corrective action below, if needed:			
Specimen Identification & Integrity: Record Review, Walkthrough & Observation			
Record evaluation: Specimens rejected due to patient collection error? If yes, how many? Document corrective action below, if needed:			
Do processes/education/instructions need to be updated for patient collection? Document corrective action below, if needed:			
Record evaluation: Specimens rejected due to lab collection/handling/processing/transport error? Document corrective action below, if needed:			
Do processes/education/instructions need to be updated for lab personnel collection/handling/processing/ transport? Document corrective action below, if needed:			
Observation: 2 patient identifiers used during collection process Document corrective action below, if needed:			
Observation: All specimens on counter and in racks labeled with 2 identifiers Document corrective action below, if needed:			
Observation: Rapid test devices labeled with 2 identifiers during testing Document corrective action below, if needed:			
Record review: Choose 5 random patient test logs/result worksheets/instrument printouts. Do they include 2 correct identifiers?			
	Patient 1:		
	Patient 2:		
	Patient 3:		
	Patient 4:		
	Patient 5:		

Complaints: Record Review	YES	NO	N/A
Did the lab receive any complaints? Document corrective action below, if needed:			
Were all complaints referred to the correct party or resolved? Document corrective action below, if needed:			
Communications: Record Review			
Were breakdowns in communication documented? Document corrective action below, if needed:			
Do processes and/or instructions need to be updated or education performed? Document corrective action below, if needed:			
Personnel Competency: Record Review			
Has the lab hired new personnel in the last year? If yes, list personnel and date of training completion below:			
Have 2 competency assessments been completed for each new personnel during the first year of hire? Document corrective action below, if needed:			
Have annual competency assessments been performed for each personnel employed longer than one year? Document corrective action below, if needed:			
Are all 6 CLIA competency criteria evaluated for each assessment performed on each testing personnel? Document corrective action below, if needed:			
Proficiency Testing (PT): Record Review			
Has the lab added any new testing to its menu? If yes, list below:			
Lab enrolled in PT for all regulated (found in Subpart I of the CLIA regulations) testing, including new tests Document corrective action below, if needed:			
Lab performs twice annual verification for unregulated analytes or for tests where PT programs are not available. List methods used other than PT enrollment below:			
For each PT survey, lab retained copies of reporting forms, printouts/result logs, attestation statements, etc. Document corrective action below, if needed:			
Attestation statements for each PT event are signed by the lab director (designee) and testing personnel Document corrective action below, if needed:			
For each PT event, results were reviewed and signed by appropriate personnel Document corrective action below, if needed:			
For any PT results <100%, the lab did the following: investigated, identified the source of error, resolved the error, evaluated patient testing since PT was performed, and documented all steps in the process Document corrective action below, if needed:			
Self-evaluation performed for any ungraded PT results received, even when an artificial score of 100% is received (non- consensus, lack of peer group, problem with samples, etc.) Document corrective action below, if needed:			
Self-evaluation performed for scores of zero received for non-participation or late submission Document corrective action below, if needed:			